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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,796	04/14/2004	Michael Kadan	3802-123-27	6667

7590 11/17/2005

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,796	KADAN ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claim 3, drawn to a HeLa-S3 cell comprising tumor specific replication-incompetent adenovirus vector having a mutation in E1a, classified in class 435, subclass 320.1.

   II. Claim 4, drawn to a HeLa-S3 cell line comprising tumor specific replication-incompetent adenovirus vector having a mutation in E1b, classified in class 435, subclass 320.1.

   III. Claims 5-17 and 19, drawn to a HeLa-S3 cell line comprising replication adenovirus vector comprising heterologous transcriptional regulatory element TRE operably linked to the E1 region and a heterologous sequence of GM-CSF, classified in class 435, subclass 320.1.

   IV. Claims 20, drawn a method for a replication-competent adenovirus using a HeLa-S3 cell comprising a replication-competent adenovirus having E1a or E1b mutation, classified in class 435, subclass 91.4.

   V. Claims 21-26, drawn to a method for producing a replication-competent adenovirus, wherein said adenovirus comprising a TER operably linked to the adenovirus early region and a heterologous coding sequence for GM-CSF, classified in class 435, subclass 69.1.

2. Claim 2 link(s) inventions Group I and II. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 2. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Claims 1 and 18 link(s) inventions Group I-II and III The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions are distinct, each from the other because of the following reasons:

5. Inventions s of group I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the invention of group I and group II are directed to different host cells and cell lines comprising different adenovirus vectors. For example, the adenovirus in the group I comprising the complementary region of adenovirus E1a, whereas the host cell for group II should comprising the complementary region of E1b. Therefore, they have different patentabilities that require different searches.

6. Inventions s of group I or II and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the invention of group I or group II with group III are directed to different host cells and cell lines comprising different adenovirus vectors. For example, the adenovirus in the group I comprising a tumor specific replication-competent adenovirus that having adenovirus early gene mutation, whereas the adenovirus contained in

group III contains a special transcriptional regulatory element operably linked to the adenovirus early region and a heterologous sequence of GM-CSF. Moreover, if the HeLa S3 cells for producing different adenovirus cited in group I and group III or group II and Group IIII because the particular cell for producing different adeovirus with different early gene deletion should contains different trans-complementary gene for the adenovirus. Therefore, they have different patentabilities that require different searches.

7. Inventions s of group IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the invention of group IV and group IV are directed to different methods for producing different adenoviruses with different ell lines. Moreover, if the HeLa S3 cells for producing different adenovirus cited in group IV and V because the particular cell for producing different adeovirus with different early gene deletion should contains different trans-complementary gene for the adenovirus. Therefore, they have different patentabilities that require different searches.

8. Inventions of Groups I or II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method for producing a replication competent adenovirus does not necessarily need to use the claimed HeLa S3 cell in group I, and they can be produced with other host cell, such as human.HEK293 cell.

9. Inventions of Groups III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method for producing a replication competent adenovirus does not necessarily need to use the claimed HeLa S3 cell in group I, and they can be produced with other host cell, such as human HEK293 cell.

10. Because these inventions are distinct for the reasons given above and the search required for Group s I is not required for Group II, restriction for examination purposes as indicated is proper, or group III not for group IV.

11. Applicants are reminded that in the Office Action the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

12. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13.

14. Claims 5and 6 are generic to a plurality of disclosed patentably distinct species comprising 1). The TRE is a TRE for hTERT, 3). The TRE is an osterocalcin TRE, 3). The TRE is a CEA TRE, 4). The TRE is a DF3 TRE, 5). The TRE is α-fetoprotein TRE, 6). The TRE is a

surfactant TRE, 7). The TRE is a tyrosinase TRE, 8). The TRE is a PRL-3 TRE, 9). The TRE is MUC1/DF3 TRE, 10). The TRE is a TK TRE, 11). The TRE is a cyclin TRE, 12). The TRE is a uPA TRE, 13). The TRE is a HER 2neu TRE, 13). The TRE is a PSA TRE and 14). A probasin TRE.

15. Claims 5and 6 also are generic to a plurality of disclosed patentably distinct species comprising species for linked regions: a) E1a; b) E1b; c). E2a; d). E2b, and e). E4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Baoqun Li

Bao Qun Li
11/11/2005